AF

PATENT
Customer No. 60,949
Attorney Docket No. 1142.0378-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
James H. PICKAR et al.	)	Group Art Unit: 1617
	)	
Application No.: 09/808,878	)	Examiner: Shengjun WANG
	)	
Filed: March 15, 2001	)	
	)	
For: HORMONE REPLACEMENT THERAPY	)	Confirmation No.: 5270
	)	

Attention: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR REHEARING

Pursuant to 37 C.F.R. § 41.52, Appellants request rehearing and reversal of the Decision on Appeal dated January 31, 2007.

The Board's decision constitutes a new ground for rejection for several reasons. First, in relying on claim 42 of the Plunkett reference as the closest prior art, the Board relied on different portions of the reference, reciting different dosages, than portions of Plunkett relied upon by the Examiner. The Board's shift to claim 42's recited dosage range of 2.5 mg/day of MPA and 0.300 mg.day of CEE as the closest prior art constitutes a new ground of rejection of Appellants' claims, for which Appellants' should be afforded a proper period for response. *See* 37 C.F.R. § 41.50(b). Additionally, the Board raised and relied upon another new rationale for its rejection of Appellants' claims

over Plunkett. Namely the Board relied on a reference (Utian et al.), which was not addressed by the Examiner in the Examiner's Answer, by Appellants in their Briefs, or by the Board at oral argument, to rebut the evidence of unexpected results presented by Appellants. As with its reliance on claim 42, the Board's reliance on the Utian reference to refute Appellants' arguments constitutes a new ground of rejection, for which Appellants should be given a fair opportunity for response.

Moreover, the Board misapprehended the data in Appellants' specification as allegedly showing that "those skilled in the art would have expected the lower dosages of MPA and CEE disclosed by Plunkett to be *unsuccessful* in controlling hot flushes." (Decision at page 7, lines 6-7, emphasis added.) This misunderstanding of Appellants' position is explicitly refuted by Dr. Lobo's First Declaration as well as Appellants' Reply Brief. Based on this misunderstanding, the Board erred in affirming the Examiner's rejection, and Appellants therefore request reconsideration and reversal of the Board's decision.

Accordingly, Appellants request that: (1) the Board acknowledge that its decision has raised grounds of rejection, and provide Appellants with a fair opportunity for response pursuant to 37 C.F.R. § 41.50(b); and (2) based on the existing record, the Board reconsider its affirmance of the Examiner's rejection related to Appellants' showing of unexpected results in view of the correct interpretation of what a person of ordinary skill in the art would have expected.

A. The Board Has Applied a New Ground of Rejection

1. The Board Has Applied a New Ground of Rejection in Relying on Claim 42 as the Closest Prior Art

The Examiner's Answer articulates the obviousness rejection over Plunkett et al. (Re 36,247), in part, as follows:

> Plunkett teaches the minimum and maximum dosages for medroxyprogesterone (MPA) and conjugated equine estrogens (CEE) to be 1 mg/day and 15 mg/day, and 0.300 mg/day and 2.5 mg/day, respectively, and the preferred dosages are 1-2.5 mg (MPA) and 0.300-0.600 mg (CEE) respectively, **see claims 34-35**, see also Table IA, col. 4, in particular.

(Page 3, emphasis added.) The Examiner's Answer further alleges that a prima facie case of obviousness has been established, in part, by stating:

> Note that Plunkett teaches that MPA can be employed at a minimum dosage of 1.0 mg and maximum dosage of 15 mg and **preferred range of 1-2.5 mg/day (claim 32)**. Note also that the claimed dosage herein, 0.3-0.45 mg of CEE, falls within the dosage range of 0.300-0.600 mg disclosed by Plunkett.

(Page 4, emphasis added.) The Examiner's Answer then alleges that the evidence of record is not sufficient to overcome the obviousness rejection, stating, in part:

> Note that in order to overcome obviousness appellant must demonstrate unexpected and significant results in comparison with **the closest prior art**, i.e., Plunkett. No such comparative data has been provided. **Appellants state that the closest example in Plunkett is a regimen comprising 0.600 mg CEE and 2.5 mg MPA. The specification on page 9 provides a comparative example between 60.625 [sic 0.625] mg of CEE, and not 0.600 mg of CEE.**

(Page 5, emphasis added.) Nowhere in the Examiner's Answer or in the rejections that preceded it did the Examiner mention claim 42 of Plunkett or the specific dosages recited in that claim.

The Board, however, in affirming the Examiner's rejection over the Plunkett reference, relies on claim 42. *See* Board decision, page 4, third from last line; page 6, line 15. Significantly, the Board criticizes Appellants' showing of unexpected results by arguing that Appellants did not compare the claimed method to the closest prior art, *i.e.,* claim 42:

> Here, Greendale [who reported the PEPI study] is not the closest prior art, The embodiment in the prior art that is closest to the claimed method is that of Plunkett's claim 42: 2.5 mg of MPA combined with 0.3 mg of CEE.

(Page 12.) As noted at oral argument, Appellants have never had an opportunity to respond to a rejection based on the "embodiment" of claim 42, since the Examiner never relied upon that embodiment. That fact alone demonstrates that the Board decision constitutes a new ground of rejection and Appellants should be allowed to present evidence rebutting that rejection.

The situation is similar to that of *In re Kumar,* 418 F.3d 1361 (Fed. Cir. 2005), where the Board in affirming the examiner's obviousness rejection over a single reference, relied upon its own calculations of various particle size ranges. The Federal Circuit, in vacating and remanding the case, pointed out:

> When a rejection for obviousness is based on overlapping values in the prior art, identification of the values deemed to overlap is material to the rejection.

Id. at 1367. The court concluded that the Board's decision based on the new calculated values constituted a new ground of rejection, in part, because the overlapping values were not identified in the examiner's rejection but only for the first time in the Board's decision. As the court stated:

> In calculating the overlapping values, the Board found facts not found by the examiner regarding the differences between the prior art and the claimed invention, which in fairness required an opportunity for response.

Id. at 1368. The court relied upon *In re Waymouth,* 486 F.2d 1058, 1060-61 (CCPA 1973), for the proposition that "a new rejection [has] occurred where the examiner and the board [reject] a claim for different reasons." *Kumar,* 418 F.3d at 1368.

In the instant case, particularly, where there is evidence of unexpected results in the original specification, identification of what the PTO considers to be the closest prior art is material to the rejection. Likewise, where the Examiner's Answer and the Board provide different rationales for rejecting the claims and criticizing Appellants' evidence of unexpected results, there has been a new ground of rejection, which deserves a full and fair opportunity for response. *See id.* Accordingly, Appellants request that the Board acknowledge the new ground of rejection so that Appellants may be afforded the opportunities available under 37 C.F.R. § 41.50(b).

2. The Board Has Applied a New Ground of Rejection in Relying on the Utian Reference to Refute Appellants' Showing of Unexpected Results

Besides relying on a different dosage range as the closest prior art, the Board decision constitutes a new ground of rejection in its rationale for rejecting Appellants' assertion that the HOPE study data described in the specification was unexpected. In

particular, the Board relies on a reference, Utian et al., which although of record and co-written by one of the named inventors, was not relied upon by the Examiner in the Answer or otherwise. *See* Board decision, pages 8-11. The Board, in particular, relies on a sentence in Utian that concludes that the "findings [of the HOPE study] are *consistent with results of previous studies* that examined the efficacy of lower estrogen dosages for relief of vasomotor symptoms," and then that "[t]he results . . . confirm the effectiveness of lower doses of CEE and MPA . . . in the context of a large clinical trial." *Id.* at page 11, lines 3-8 (emphasizing and quoting Utian, pages 1073-74). Since the Examiner never relied on this reference, Appellants have not had an opportunity to deal with the issue raised for the first time in the Board's decision.

The reliance on Utian represents, perhaps even more clearly than the reliance on claim 42, that the Board in its decision "went off on its own" in considering the Plunkett disclosure, Appellants' claimed method, and evidence of unexpected results. *See Kumar,* 418 F.3d at 1367 (quoting *In re Eynde,* 180 F.2d 1364, 1371 (CCPA 1973). Accordingly, for this additional reason, the Board's decision constitutes a new ground of rejection for which Appellants should be given a full and fair opportunity for response under § 41.50(b).

B. <u>The Board Has Misunderstood Appellants' Showing of Unexpected Results</u>

In addition to criticizing Appellants' evidence of unexpected results as testing the wrong dosage and as being refuted by Utian, the Board in its decision misapprehends Appellants' position as to what a person of ordinary skill in the art would have expected from using the lower dosages of MPA and CEE disclosed in the Plunkett reference. On

page 7, lines 5-7, the Board construes Appellants' position as being "that those skilled in the art would have expected the lower dosages of MPA and CEE disclosed by Plunkett to be **unsuccessful** in controlling hot flushes" (emphasis added).

In fact, Dr. Lobo testified in his First Declaration as follows:

> I and others expected that the study would show that there would be a **dose response** such that the lower combination doses of CEE and MPA would have **some effect** in reducing the number and severity of hot flushes compared with the placebo, **but far less of an effect** than the standard dose of CEE 0.625 plus 2.5 mg MPA.

(Pages 4-5, par. 12 (emphasis added); *see also* Reply Brief, page 7.) Regardless of whether the Board finds this statement credible or persuasive (*see* Board decision, page 10), this statement, relied upon in Appellants' Reply Brief, shows that Appellants' position was not that those of skill in the art would have expected the lower dosages to be **unsuccessful** or **ineffective**, as the Board has erroneously understood. Rather, the evidence establishes that those of skill in the art would have expected a **decrease** in the dosage to result in a **decrease** in (not lack of) activity, *i.e.,* would have expected a dose-dependent response. Because, the Board has misapprehended Appellants' position as to what would have been expected by a person of skill in the art, it reached an erroneous conclusion in its obviousness analysis. Accordingly, Appellants request reconsideration and reversal of the decision.

C. Conclusion

For all of these reasons, Appellants believe that: (1) the Board's reliance on claim 42 of Plunkett and on the Utian reference constitute a new ground of rejection over

Plunkett, for which Appellants should be given a fair opportunity for response pursuant to 37 C.F.R. § 41.50(b), and (2) even on the existing record, the Board's decision incorrectly interpreted Appellants' showing of unexpected results and should therefore be reversed.

Please grant any extensions of time required to enter this reply brief and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

Dated: March 30, 2007

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